IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

LUANN PARKER, Case No. C-1-00-766 :

> Plaintiff, :

> > JUDGE Susan J. Dlott :

v. :

> LIST OF EXHIBITS ATTACHED :

Filed 09/24/2004

AVENTIS PASTEUR INC., MEMORANDUM IN :

> Defendant. **OPPOSITION TO DEFENDANT'S** :

> > MOTION FOR SUMMARY :

JUDGMENT :

- Exhibit 1 Affidavit of Dr. Scott E. Woods, M.D., M.P.H., M.Ed., F.A.A.F.P. and his Curriculum Vitae.
- Exhibit 2 Office Records of Stephen Brewer, M.D., Emergency Room Report October 13, 1998.
- Exhibit 3 Office Records of Stephen Brewer, M.D., October 15, 1998. Letter from Dr. Rorick to Dr. Brewer.
- Exhibit 4 Hospital Records of Luann Parker at Bethesda North Hospital, 10/21/98 10/25/98.
- Exhibit 5 Hospital Records of Luann Parker at Bethesda North Hospital, 10/28/98 11/9/98.
- Exhibit 6 Hospital Records of Luann Parker at Bethesda North Hospital, 11/10/98
- Exhibit 7 Hospital Records of Luann Parker at Bethesda North Hospital, 11/14/98.
- Exhibit 8 Hospital Records of Luann Parker at Bethesda North Hospital, 12/26/98.
- Exhibit 9 Hospital Records of Luann Parker at Bethesda North Hospital, 1/5/99.
- Exhibit 10 Affidavit of Dr. David A. Greisemer, M.D. and his Curriculum Vitae.
- Exhibit 11 Defendant's Neurological Expert Report

AFFIDAVIT OF SCOTT E. WOODS MD, MPH, M.Ed., FAAFP

Hamilton County, Ohio

Scott E. Woods MD, MPH, M.Ed., FAAFP, being under oath or affirmation, says:

- 1. I am a physician licensed to practice medicine in the State of Ohio.
- 2. I am board certified by American Board of Family Practice.
- 3. I received Masters Degree in Public Health in Epidemiology from The University of North Carolina at Chapel Hill.
- 4. I am the Director of Epidemiology at Bethesda Family Medicine Residency Program.
- 5. The attached *curriculum vitae* accurately depicts my professional qualifications.
- 6. It is my opinion based upon reasonable scientific and medical certainty that influenza vaccine for a given year is not amenable to prospective epidemiological studies specifically for rare adverse effects.

WITNESS affigant's signature on this 2 _day of September 2004.

subscribed before me a notary public in and for the State of Ohio on/the date shown above

MICHELE LOUISE MAGNUS Attorney at Law Notary Public, State of Ohio Commission Has No Expiration Section 147.03 R.C.

Curriculum Vitae

Scott E. Woods MD, MPH, M.Ed., FAAFP

liverdoctor@yahoo.com

Home Address: 6644 San Mateo Drive Cincinnati, Ohio 45069 (513) 759-9105

Birthplace: Cincinnati, Ohio Birthdate: December 11, 1960

Spouse: Celina Woods Children: Kasi & Amy

Lifelong Professional Goal

To be the inspirational leader of a family practice residency program.

Current Professional Position

Bethesda Family Practice Residency Program

1999-

present

Director of Epidemiology Director of Recruitment

4411 Montgomery Rd, Suite 200, Cincinnati, Ohio 45212

Large research, teaching and patient care responsibilities in a 6-6-6 program.

Research Interest: The influence of gender & race on health outcomes.

Surgical Faculty, Good Samaritan Hospital General Surgical Residency Program 2000-present

Large research and lecturing responsibilities

Primary Investigator, SELECT Trial, Bethesda Hospital Study Center.

2000-

2012

Large randomized clinical trial to prevent prostate cancer, sponsored by the NCI

Previous Professional Positions

The University of North Carolina at Chapel Hill, Adjunct Clinical Instructor

1995-

1999

Patient care, research and teaching responsibilities.

Cary Primary Care, Private practice, Cary, North Carolina 1995-1999

Full spectrum family practice

Fellowships

NRSA Primary Care Research Fellowship, (PGY 6 – 8)

1992-

1995

The University of North Carolina at Chapel Hill

Robert Wood Johnson Core Curriculum

	Three-year research fellowship sponsored by the National Institute of Health	
1992	Faculty Development Fellowship (PGY 5)	1991-
respon	Duke University Medical Center Department of Family Medicine Full-time fellowship with teaching, patient care, administrative and research sibilities. lency	
1991	Chief Resident (PGY 4), Bethesda Hospital, Cincinnati, Ohio	1990-
	Junior faculty position as an attending physician.	
1990	Resident in Family Medicine, Bethesda Hospital, Cincinnati, Ohio	1987-
1997	Diplomat of the American Board of Family Practice	1990-
	Recertified, ABFP	1997-
2004	Recertified, ABFP	2004-
2011	Diplomat of the National Board of Medical Examiners Medical License, State of Ohio	1988 1988-
presen		
Educ	cation	
1998	Masters in Education in Curriculum and Instruction	1993-
1770	The University of North Carolina at Chapel Hill	
(publis	Thesis: A Qualitative Evaluation of the Faculty Development Fellowship at UNC shed)	
	Masters in Public Health in Epidemiology 1992-1995	
	The University of North Carolina at Chapel Hill Thesis: Collegial Networking and Faculty Vitality: A case-control study (published)	ed)
1007	Doctor of Medicine	1983-
1987	The University of Cincinnati College of Medicine Graduated in top third of class	
1000	Bachelor of Science in Biochemistry	1979-
1983	Xavier University, Magna Cum Laude	

Thesis: Zinc radioactivity and its deposition in fish organ systems

Publications

- Woods S, Smith JM, Sohail S, Sarah A, Engle A. The Influence of Type 2 Diabetes Mellitus in Patients Undergoing Coronary Artery Bypass Graft Surgery: An Eight-year Prospective Cohort Study. Chest 2004 (In press).
- Woods S, Smith JM, Engle A, Hiratzka L. Predictors of Stroke in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Prospective, Nested, Case-Control Study. J Stroke Cerebrovascular Dis. 2004 (in press).
- Lewis C, Woods S, Lohr J, Poynter M, Engel A, Rusche J. Level of Education and Patient Opinion: Significant Differences in Perceptions of Health Care. Current Surgery. 2004 (In press).
- Nash A, Woods S, Awada S. Pheochromocytoma. Resident and Staff Physician. 2004 (In press).
- Silva W, Kleeman S, Segal J, Pauls R, Woods S, Karram M. Effects of A Full Bladder and Patient Positioning of Pelvic Organ Prolapse Assessment. Obstetrics and Gynecology 2004 (In press).
- Berson, A, Smith JM, Woods S, Hasselfeld K, Hiratzka L. Off-pump versus on-pump coronary artery bypass surgery: does the pump influence outcomes? J Am Coll Surg 2004;199:102-108.
- Recht M. Smith JM, Woods S. Engle A. Hiratzka L. Predictors and outcomes of gastrointestinal complications in patients undergoing coronary artery bypass graft surgery: A prospective, nested case-control study. J Am Coll Surg 2004;198:742-747.
- Powell, K., Smith JM, Woods S, Hendy MP, Engle A. Coronary Artery Bypass Grafting in Patients with Dialysis-Dependent End Stage Renal Disease. J Card Surg 2004 (In press).
- Woods S, Heidari Z. The influence of gender on patient satisfaction. J Gender-specific Med 2003;6:30-35.
- Awaida JP, Woods S, Doerzbacher M, Gonzales Y, Miller T. Four Cut Sinus CT in Screening for Sinus Disease. Southern Medical Journal 2004;97:18-20.
- Woods S, Smith JM, Engel A, Hiratzka L. Predictors of Stroke in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Prospective, Nested, Case-Control Study. Chest 2003;124(4):159s.
- Recht M, Smith JM, Woods S, Engle A, Hiratzka L. Predictors and outcomes of gastrointestinal complications in patients undergoing coronary artery bypass graft surgery: A prospective, nested case-control study. Chest 2003;124 (S):159s.

- Woods S, Smith JM, Engel A, Hiratzka L. Predictors of Stroke in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Prospective, Nested, Case-Control Study. Circulation 2003;107;e131.
- Woods S, Narayanan K, Engel A. Colon Cancer and Gender: Do we find the disease earlier in either Sex? J Women's Health 2003;12;425.
- Avelar E, Woods S, Doerzbacher M, Gonzales Y. The Influence of Multiple variables on the Prevalence of aspirin Prescribing in Patients with known Coronary Artery Disease. HEARTDRUG 2003;3:82-86.
- Awada S, Grisham A, Woods S. A Large Dopamine-secreting Pheochromocytoma. Southern Medical Journal 2003;96:914-917.
- Woods S, Sorscher J, King J. The Influence of Gender in Young Adults admitted for Asthma. J Women's Health 2003; 12:481-485.
- Rivera E, Woods S. The prevalence of asymptomatic C. difficile in a nursing home population. J Gender-specific Med 2003;6[2]:27-30.
- Woods S, Noble G, Smith JM, Hasselfeld K. The Influence of Gender in Patients Undergoing Coronary Artery Bypass Graft Surgery: An eight-year prospective Hospitalized Cohort Study. J Am Coll of Surg 2003; 196: 428-434.
- Woods S. What Cancer are you at Risk to Develop at your Age? (Female) Vibrant Life 2002;6:8-13.
- Rosenbaum C, Woods S, Hasselfeld K. The correlation of the change in the International Normalized Ratio and the need to decrease the Dosage of Coumadin. Orthopedics 2002;25:1359-1363.
- Berson, A, Smith JM, Woods S, Hasselfeld K, Hiratzka L. Off-pump versus on-pump coronary artery bypass surgery: does the pump influence outcomes? Chest 2002;122:40**S**.
- Woods S, Smith JM, Noble G, Hasselfeld K, Hiratzka L. The Influence of Gender in Patients undergoing Coronary artery Bypass Surgery. Chest 2002;122:97S.
- Johnson M, Smith JM, Woods S, Hendy MP, Hiratzka L. Cardiac Surgery in Octogenarians: Does age alone influence outcomes? Chest 2002;122:41S.
- Berson, A. Smith JM, Woods S, Hasselfeld K, Hiratzka L. Off-pump versus on-pump coronary artery bypass surgery: does the pump influence outcomes? J Am Coll Surg 2002;195:s24.
- Smith JM, Woods S, Hasselfeld K, Engel A, Hiratzka L. The Influence of Race in Patients undergoing Coronary artery Bypass Surgery: A Prospective Hospitalization Study. Circulation 2002;102:P116.
- Woods S, Smith JM, Noble G, Hasselfeld K, Hiratzka L. The Influence of Gender in

- Patients undergoing Coronary artery Bypass Surgery. Circulation 2002;102:P89.
- King J, Woods S, Sorscher J. The Influence of Gender in Young Adults admitted for Asthma. J Women's Health & Gender-Based Med 2002;11:317(P-4).
- Woods S. The Influence of Gender in Patients undergoing Coronary artery Bypass Surgery: A Prospective Hospitalization Study. J Women's Health & Gender-Based Med 2002;11:317 (P-1).
- Weinberg E, Woods S, Grannan K, Hendy MP. The Influence of the Gender of the Surgeon on Surgical Procedure Preference for Breast Cancer. Amer Surg 2002;68:398-400.
- Woods S. What Cancer are you at Risk to Develop at your Age? (Male) Vibrant Life 2002;3:24-28.
- Woods S, Chandran P. The Influence of Gender on Cardiovascular Outcomes in Patients with an Acute Myocardial Infarction: A Hospitalized Cohort Study. J Fam Prac 2002;51:237-240.
- Woods S. Preventing Prostate Cancer for our Sons and Grandsons: Can Selenium and Vitamin E lower the risk? Vibrant Life 2002;1:22-23.
- Powell, K, Smith JM, Woods S, Hendy MP. Coronary Artery Bypass Grafting in Patients with Dialysis-Dependent End Stage Renal Disease. J Am Coll Card 2002;39:418A.
- Woods S. A Qualitative Assessment of One Cohort from the University of North Carolina Faculty Development Fellowship. Fam Med 2002;34:128-133.
- Woods S., Raju U. Maternal Smoking and the Risk of Congenital Birth Defects: A Cohort Study. J Amer B Fam Pract 2001;14:330-4.
- Woods S. Reply, Letter to the Editor. J Amer B Fam Pract 2002;15:85-86.
- Woods S. Can Aspirin Prevent Coronary Heart Disease in Women? Women's Health in Primary Care 1998;1:210-220.
- Woods S., Reid A., Arndt J., Curtis P., Stritter F. Collegial Networking and Faculty Vitality. Fam Med 1997;29:45-49.
- Woods S., Griggs G. A Curriculum for Teaching Faculty Budgeting and Financial Management Skills. Fam Med 1994;26:587-589.
- Lewis D., Woods S. Fetal Alcohol Syndrome. American Family Physician 1994;50:1025-1032.

- Woods S. Aspirin and the Primary Prevention of Myocardial Infarction in Women. Arch Fam Med. 1994;3:361-364.
- Woods S., Hitchcock M., Meyer A. Alcoholic Hepatitis. American Family Physician 1993;47:1171- 1178.
- Meyer A., Woods S. Hepatitis. Monograph, American Family Physician Home Self No. 163, 1992. Assessment,
- Woods S., Colon F. Wilson's Disease. American Family Physician 1989;40:171-178.

Research Presentations

- "The Influence of Gender in patients diagnosed with Colon Cancer." The Society of Teachers of Family Medcine Annual spring convention. Toronto, Canada May 13 - May 16, 2004.
- "Predictors of Stroke in patients undergoing CABG surgery" Chest, Orlando, FL October 28-30,2003.
- "Predictors and outcomes of gastrointestinal complications in patients undergoing coronary artery bypass graft surgery: A prospective, nested case-control study." Chest, Orlando, FL, October 28-30,2003.
- "The Influence of Gender in patients diagnosed with Colon Cancer." AAFP Scientific Assembly. New Orleans, Oct 1 – Oct 6, 2003.
- "The Influence of Gender in patients diagnosed with Colon Cancer." 11th Annual Congress on Women's Health. Hilton Head Island. May 30 - June 2, 2003.
- "Predictors of Stroke in patients undergoing CABG surgery" American Heart Association Asia Pacific scientific Forum, Honolulu, Hawaii, June 8-10,2003.
- "The Influence of Gender on Cardiovascular Outcomes in Patients Undergoing CABG surgery: A Hospitalized Cohort Study." NAPCRG, New Orleans, LA, November 17-20, 2002.
- "The Influence of Gender on Cardiovascular Outcomes in Patients Undergoing CABG surgery: A Hospitalized Cohort Study." American College of Chest Physicians, San Diego, CA November 4 -8, 2002.
- "Cardiac Surgery in Octogenarians: Does Age Alone Influence Outcomes?." American College of Chest Physicians, San Diego, CA November 4-8, 2002.
- "Off-pump Versus On-pump Coronary Artery Bypass surgery: Does the pump Influence Outcome." American College of Chest Physicians, San Diego, CA November 4 -8, 2002.

- "Off-pump Versus On-pump Coronary Artery Bypass surgery: Does the pump Influence Outcome." American College of Surgery, San Francisco, CA, October 6-10, 2002.
- "The Effect of Race on CABG Surgery" 4th Scientific Forum on Quality of Care and Outcomes research in Cardiovascular Disease and Stroke. American Heart Association, October 13, 2002, Washington DC
- "The Influence of Gender in Patients undergoing CABG Surgery: A hospitalized Cohort Study" 4th Scientific Forum on Quality of Care and Outcomes research in Cardiovascular Disease and Stroke. American Heart Association, October 13, 2002, Washington DC
- "The Influence of Gender on Cardiovascular Outcomes in Patients Undergoing CAGB surgery: A Hospitalized Cohort Study." Congress on Women's Health, Hilton Head Island, SC May 18-21, 2002.
- "The Influence of the Gender of the Surgeon on surgical procedure preference for breast cancer." Congress on Women's Health, Hilton Head Island, SC May 18-21, 2002.
- "Coronary artery by-pass surgery in patients with dialysis dependent end-stage renal failure: A nested case-control study." Amer Coll of Card, Atlanta, GA March 14-17, 2002.
- "Maternal Smoking and the Risk of Congenital Birth Defects." AAP Annual Spring Conference, San Francisco, CA, October 19-24, 2001.
- "The Influence of Gender on Cardiovascular Outcomes in Patients with an Acute Myocardial Infarction: A Hospitalized Cohort Study." AAFP Scientific Assembly, Atlanta, GA, October 3 -7, 2001.
- "The Influence of Gender on Cardiovascular Outcomes in Patients Undergoing CAGB surgery: A Hospitalized Cohort Study." AAFP Scientific Assembly, Atlanta, GA, October 3 -7, 2001.
- "Maternal Smoking and the Risk of Congenital Birth Defects." STFM Annual Spring Conference, Denver Co, April 28 - May 2, 2001.
- "The Influence of Gender on Cardiovascular Outcomes in Patients with an Acute Myocardial Infarction: A Hospitalized Cohort Study." STFM Annual Spring Conference, Denver CO, April 28 - May 2, 2001.
- "The Influence of Gender on Cardiovascular Outcomes in Patients with an Acute Myocardial Infarction: A Hospitalized Cohort Study." Bristol-Myers Squibb National Family Medicine Research Forum, Ft. Lauderdale, Fl., December 3, 2000.
- "International Medical Graduates in Family Practice Residency Programs: Facing Our Prejudice." 33rd Annual STFM Spring Conference, Orlando, Fl., May 5, 2000.

"Developing the Faculty Developer for Success Beyond 2000" 32nd Annual STFM Spring Conference, Seattle, April 28, 1999.

"Qualitative Case Study of the Faculty Development Fellowship at The University of Carolina at Chapel Hill" 32nd Annual STFM Spring Conference, Seattle, April 28, 1999.

"Career Dilemmas Encountered By Family Medicine Faculty" Mead Johnson Family Medicine Research Forum, Ft. Lauderdale, Fl., December 3, 1992.

Grant Support

American Cancer Society, Ohio Academy of Family Physicians, \$1000 Cancer Research/Resident Education Grant, 2004

Bethesda Foundation, \$118,200 for Bethesda Family Practice Sports Medicine Fellowship Start-up Funds, 2003.

Bethesda Foundation, \$176,000 for "Chromium and Gestational Diabetes" 2003.

Southwest Ohio Association of Family Physicians, \$500 for "The prevalence of Assymptomatic C. diff. in a nursing home population" 2000.

Bethesda Foundation, \$3500 for "The prevalence of assymptomatic C. diff. in a nursing home population" 2000.

UNC Chapel Hill, School of Medicine, \$6,000 for master's thesis, "Qualitative Case Study of the Faculty Development Fellowship at The University of North Carolina at Chapel Hill" 1997.

Community Service

1999	Volunteer, Agape Corner, Durham, NC	1993-
1999	Volunteer Physician SHACC Clinic, Chapel Hill, NC	1992-
	Meals on Wheels, Community volunteer, Durham, NC	1992
1992	Medical Director, Madison Place Volunteer Fire Department	1989-
	Wyoming Volunteer Fire Department	1976-

1983

Volunteer Fireman and Emergency Medical Technician

Honors

Third Place, Attending Division, Forth Annual TriHealth Research Competition	2004
Nominee, Innovator Category, 7th Annual Health Care Heroes Awards One of 53 healthcare professionals in the Cincinnati area nominated in or of six categories, sponsored by the Cincinnati Business Courier.	2004 ie
Fellow, American Academy of Family Physicians	2003
First place, Clinical Science Research Award Ohio Chapter of the American College of Surgeons	2003
Second Place Research Award, 11th Annual Congress on Women's Health Hilton Head Island, May 2003.	2003
First Place, Attending Division, Third Annual TriHealth Research Competition	2003
Teacher of the Year, Bethesda Family Practice Residency Program 2002	
Second Place, American Academy of Family Physicians Scientific Assembly 2001	
Research Presentations Oct. 7, 2001, Atlanta, GA.	
First Place, Attending Division, First Annual TriHealth Research Competition	2001
Teacher of the Year, Bethesda Family Practice Residency Program 2000	
Finalist, Walter Kemp Award, American Family Physician 1995	
For Fetal Alcohol Syndrome 1994;50:1025-1032.	
Letter of Commendation, Children's Hospital Medical Center Cincinnati, Ohio	1985
Honorary Fireman, City of Wyoming	1984
Magna Cum Laude, Xavier University	1983
Outstanding Leadership and Volunteer Service Award. City of Wyoming	1977

Professional Affiliations

The Society of Teachers of Family Medicine present

1993-

American Academy of Family Physicians 1983-present

Activities and Hobbies

Antique sports cars (I own an original 1965 Mustang Fastback), music, running, and reading.

BETHESDA TRIHEALTH GOOD SAMARITAN CINCINNATI, OHIO

ROOM # : DER-N

EMERGENCY ROOM REPORT

PATIENT NAME : PARKER LUANN E

CASE NUMBER : 924208

DOCTOR : KURT KNOCHEL, MD

DICTATING DOCTOR:

REFERRING DOCTOR :

CONSULTING DOCTOR: Brewer S. C. Fam Madeira Fam Pracmd, MD

DATE: 10/13/98

CHIEF COMPLAINT: Headache.

HISTORY: A 52-year-old female yesterday had a headache that she saw her physician for. She said it actually started a couple of days ago, was gradual in onset. Had been to the neck and occipital scalp. Now today is localized in the right frontal area. It is sharp. She cannot identify any exacerbating or relieving factors. It does not feel like migraines that she has had in the past. She also has noted feeling numb over the whole body today, particularly in the hands. She could not identify any particular fingers that were more numb than any others. She has not noticed any weakness, but has noticed some difficulty in thinking, in that yesterday when she went to Wendy's, she just didn't realize that she would have to roll down her window to order a Coke and this morning when she was driving home, she couldn't decide how to drive into her driveway. It was just hard for her to judge where to turn. She has not noticed any problems like this in the past.

PAST MEDICAL HISTORY: Is remarkable for diabetes and hypertension.

CURRENT MEDICATIONS: Midrin, Adalat, Clonidine, and Glucotrol.

ALLERGIES: She has an allergy to codeine, which is really a gastric intolerance.

SOCIAL HISTORY: Lives at home.

REVIEW OF SYSTEMS: No fevers, chills, chest pain, shortness of breath, focal numbness or weakness, leg pain or swelling.

PHYSICAL EXAMINATION: A 52-year-old female in no apparent distress. Blood pressure: 145/83. Temp: 97.9°. Pulse: 76. Respirations: 20. Head: Normocephalic, atraumatic. ENT: The tympanic membranes and oropharynx are clear. Neck: Supple, no jugular venous distention or bruits. Respiratory: Lungs clear. Cardiovascular: Heart regular rate and rhythm, no click, murmur, gallop, or rub. Abdomen: Soft, nontender, no palpable masses, no hepatosplenomegaly. Extremities: Good peripheral pulses. Neurologic: Alert, oriented x 3. Cranial nerves 2-12 are normal. Ocular fundi are benign. Visual fields are intact to confrontation. Grip strength: Equal. No pronator drift. Cerebellar function intact, finger-to-nose. Leg strength: Symmetrical.

PAGE 1

EXHIBIT

BETHESDA TRIHEALTH GOOD SAMARITAN CINCINNATI, OHIO

ROOM # :

EMERGENCY ROOM REPORT

PATIENT NAME

PARKER LUANN E

CASE NUMBER

924208

DOCTOR

: KURT KNOCHEL, MD

Gait: Normal.

ED COURSE: Due to the patient's complaint of difficulty thinking along with the headache that was unusual for her, we did go ahead and get a CT of the head and that has shown some atrophy, which is a bit unusual for a lady of age 52. We also found her glucose to be elevated at 342.

DISCHARGE INSTRUCTIONS: The case was discussed with Dr. Weiskittel, who is on call for Dr. Brewer, and the patient, at this point, will be given Vicodin for pain, is to follow up with him in the office in the next couple of days for further evaluation of the atrophy. There is a bit of concern that she may have an early dementia.

ASSESSMENT: Headache.

PLAN: As above.

KURT KNOCHEL, MD

JSP

D: 10/13/98 T: 10/17/98

#5THESDA HOSPITALS • CINCINNATI, OHIO

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11/10/98 D3:44 AM

PAGE 002 (QAXNOR)

MEDICAL RECORDS TRANSCRIPTION

PARKER LUANN E

1199802772403 MM#:738579

BETHESDA TRIHEALTH GOOD SAMARITAN CINCINNATI, OHIO

ROOM # : B44401

CONSULTATION REPORT

PATIENT NAME

: PARKER LUANN E

CASE NUMBER

: 073906

HAD SHINGLES.

PERSONAL/SOCIAL HISTORY: SHE IS DIVORCED. TWO CHILDREN. NO HISTORY

ALLERGIES: CODEINE.

MEDICATIONS: SHE IS NOW ON ORAL DEXAMETHASONE 4 MG Q 6 HOURS, BLOOD PRESSURE MEDICATION, AND ALSO HER INSULIN AND GLIPIZIDE.

PHYSICAL EXAMINATION:

HEENT: MOUTH IS CLEAR. NECK SUPPLE.

SHE MOVES ALL EXTREMITIES.

OF SMOKING OR ALCOHOL USE.

CHEST/LUNGS: CLEAR BREATH SOUNDS BILATERALLY.

HEART: REGULAR RATE AND RHYTHM, NO MURMURS.

ABDOMEN: SOFT AND NONTENDER.

HER GAIT IS EXTREMELY UNSTEADY AND ATAXIC. WHEN SHE SITS UP IN BED SHE FEELS VERY UNSTEADY AND COMPLAINED OF HEADACHE AT THAT TIME.

ASSESSMENT: PLAN: SEVERE ATAXIA, STATUS POST A FLU SHOT. I DID CONTACT THE CDC AND I HAVE TALKED TO DR. CAROLYN BRIDGES, ONE OF THE DOCTORS RESPONSIBLE FOR THE BUNCH OF FLU VACCINE, AND SHE STATES THAT THIS WHOLE PICTURE COULD BE SECONDARY TO THE FLU SHOT ALTHOUGH IS VERY RARE SUCH REPORT. UNFORTUNATELY, THAT COULD BE A REACTION TO THE FLU SHOT OR IT COULD BE COINCIDENTAL THAT THE PATIENT HAS ACUTELY DEVELOPED MS AFTER THE FLU SHOT, OR SHE COULD HAVE ANOTHER INFLAMMATORY VERSUS A DEMYELINATING PROCESS. VASCULITIS IS STILL A CONSIDERATION AND WE ORDERED ANCA. HER SED RATE WAS ONLY 10. WOULD BE UNLIKELY ACUTE ENCEPHALITIS SECONDARY TO HERPES VIRUS WITH THE FINDINGS OF THE MRI SCAN PLUS THE FACT THE PATIENT HAS BEEN AFEBRILE, ETC. HOWEVER, WE WILL ORDER SOME HERPES TITERS GIVEN THE FACT THE RECENT REPORT RAISES SOME SORT OF SUSPICION BETWEEN MS AND HERPES INFECTION.

THANK YOU VERY MUCH FOR ALLOWING US TO PARTICIPATE IN THE EVALUATION. AND CARE OF THIS PATIENT. SINCERELY YOURS,

Document 30-2

Filed 09/24/EXHIBITPage

MR-18-4385 11/18/98 11:55 AM

BETHESDA HOSPITAL

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PARKER LUANN E SEX:F AGE: 52 09980277-2405 ADM DATE: 11/14/98 DAVLIN ERIN MD MM#:739310 MS:D

五 * **袋菜蒸蒸**

DISCH DATE: 11/17/98

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AKA: SOCIAL SEC#:284-44-6073 RACE:W STREET:4747 HUNT ROAD

PT CLASS:0 COUNTY: HAM RELIGION: PRT

CITY/ST:CINCINNATI,OH ZIP:45242 PHONE: 513-9843928

BIRTHDATE: U1/18/46 CHURCHE

EMPLOYER NAME: RETIRED MAIDEN NAME:

EMP STREET: MAIDEN NAME RETAINED: EMP C/S/Z: OCCUPATION:

EMP PHONE: HOW LONG: INFO RELEASED: Y

ADM DIAG: PROBABLE DEEP VEIN THROMBOSIS LT LEG

PROCEDURE:

LAST VISIT DATE: LAST DISG DATE: LMP:

ADMIT PHYSICIAN: DAVLIN ERIN MD 1793

CONS/PRIMARY CARE MD:CNA MD. 1564

ADMIT TYPE:1 ROOM/BED: ACCOM:1 SERV: HED FIN CL:3

TIME:

ADMIT TIME: D8:48PM ADMIT SAME DAY

PT AUTHORIZES PHONE: YES PT AUTHORIZES TV W/BASIC SERV

UB TYPE:81

AD SOURCE: 7

REF FACILITY:

SPOUSE

NAME:

WORK PHONE: EMPL NAME:

EMPL STREET:

EMPL C/S/Z:

NEAREST RELATIVE

NAME : CORUM TRUDY

STREET:

CITY/ST/ZIP:

PHONE HOME:513-7316114 WORK:

RELATIONSHIP: T

RESPONSIBLE PARTY

NAME:PARKER, LUANN E

STREET: 4747 HUNT ROAD

CITY/ST:CINCINNATI,OH ZIP: 45242 PHONE: 513-9843928

RELATIONSHIP:P SOCIAL SEC#: 284-44-6073

EMP NAME: RETIRED

EMP STREET:

EMP C/S/Z:

PHONE: OCCUPATION: HOW LONG:

ACCIDENT/CRIME DATA

NATURE OF ACCIDENT:

ACCIDENT DATE: ACCIDENT TIME:

ACCIDENT PLACE:

AMERICAN DISABILITY ACT: N

PRIMARY CARE MD ADDRESS:

B4-NX-8328 BETHESDA HOSPITAL

MEDICAL RECORDS TRANSCRIPTION 12/28/98 10:17 PM PARKER LUANN E

(ODOLNN) PAGE DD1

099802772360 B44701 MM#:741065

BETHESDA HOSPITAL CINCINNATI, BHIO

ROOM # : 844701

HISTORY AND PHYSICAL

PATIENT NAME : PARKER LUANN E

CASE NUMBER 741065

DOCTOR : STEPHEN C. BREWER, MD

DICTATING DOCTOR : CARBON COPIES :

DATE OF ADMISSION: 12/26/98

DATE OF BIRTH: 01/18/46

INFORMANT: PATIENT'S SISTER.

HISTORY OF PRESENT ILLNESS: A 52-YEAR-OLD WHITE FEMALE WHO WAS RECENTLY HOSPITALIZED X 2 FOR POST FLU SHOT SYNDROME, WHICH CAUSED ATAXIA AND BIZZINESS. THE PATIENT WAS ALSO HOSPITALIZED FOR RECENT DVT OF LEG.

THIS 52-YEAR-OLD WHITE FEMALE HAS BEEN TRIED TO BE WEANED FROM HER DECADRON FOR CEREBRITIS. THE PATIENT HAS BEEN TAKING A TOTAL OF 6.5 MG A DAY. FOUR DAYS AGO, THE PATIENT STARTED TO SAY INAPPROPRIATE THINGS SUCH AS SPEAKING AND TALKING TO HER DEAD MOTHER. SHE HAS ALSO BEEN NOTED TO HAVE INCREASED MOVEMENT OF HER BODY, WHICH SHE STATES WERE BEING MOVED BY HER DEAD MOTHER. THE PATIENT HAS ALSO BEEN NOTED TO BE SCREAMING AND VERY INAPPROPRIATE AT HOME. THE PATIENT HAS BEEN QUITE COMBATIVE. THE PATIENT WAS TAKEN TO THE EMERGENCY ROOM THE DAY PRIOR TO ADMITTED AND LAB STUDIES WERE ALL NORMAL. THE PATIENT WAS FOUND ON THE FLOOR, ROCKING BACK AND FORTH, STATING THAT SHE WAS TO CHANGE THE FLOW OF HER INTERNAL FLUIDS FROM RIGHT TO LEFT RATHER THAN UP AND DOWN. SHE WOULD DO THIS FOR SEVERAL HOURS AT A TIME. IT WAS DECIDED TO ADMIT THE PATIENT AT THIS TIME.

PAST MEDICAL HISTORY:

- 1. HISTORY OF TYPE II DIABETES.
- HISTORY OF HYPERTENSION. 2.
- HISTORY OF POST FLU SHOT CEREBRITIS, VERY SLOWLY RESOLVING.

MEDICATIONS: TAKES ATIVAN P.R.N., PROCARDIA XL 30 MG Q.D., DECADRON 2 MG IN THE MORNING, 4 MG IN THE EVENING. COUMADIN 2.5 MG A DAY, GLUCOTROL XL 10 MG Q.D., CLONIDINE 0.2 MG AT BEDTIME, ATENOLOL 50 MG Q.D. SHE IS ALSO ON A SLIDING SCALE INSULIN.

FAMILY HISTORY: MOTHER AND FATHER HAD HISTORY OF HEART DISEASE AND HYPERTENSION. FATHER HAD A HISTORY OF CANCER.

SOCIAL HISTORY: NEGATIVE FOR SMOKING AND ALCOHOL USE.

MEDICAL RECORDS TRANSCRIPTION 12/28/98 10:17 PM (ODOLNN) PAGE 002 PARKER LUANN E 099802772360 B44701 MM#:741065 BETHESDA HOSPITAL

REVIEW OF SYSTEMS: CARDIOPULMONARY NEGATIVE. GI NEGATIVE. GU NEGATIVE. NEURO; STATES THAT SHE HAS DIFFICULTY IN THE MORNING, ESPECIALLY TRYING TO GET OUT OF BED. THE PATIENT STATES THAT SHE IS STILL UNSTEADY OF GAIT.

PHYSICAL EXAMINATION: THIS IS A MIDDLE AGED CUSHINGOID APPEARING WHITE FEMALE WHO IS ALERT TO TIME AND PLACE.

HEAD, EYES, EARS, NOSE & THROAT: HEAD CUSHINGOID. EYES; PUPILS ARE EQUALLY ROUND, AND REACTIVE TO LIGHT AND ACCOMMODATION. ENT WITHIN NORMAL LIMITS.

NECK: FULL, NO MASSES.

CHEST: LUNGS CLEAR TO PERCUSSION AND AUSCULTATION. HEART: REGULAR RHYTHM WITHOUT MURMURS OR GALLOPS. ABDOMEN: SOMEWHAT OBESE. NO ORGANOMEGALY APPRECIATED. EXTREMITIES: BILATERAL 2+ EDEMA BILATERALLY WITH STRIAE BOTH LEGS. NEUROLOGICAL EXAMINATION: THE PATIENT GIVES STORY AS STATED IN PRESENT HISTORY. THE PATIENT STATES THAT SHE WOULD ROCK BACK AND FORTH TO TRY TO MOVE HER FLUIDS FROM SIDE TO SIDE. THE PATIENT'S GAIT IS SOMEWHAT UNSTEADY. NORMAL MOTOR AND SENSORY. CRANIAL NERVES II-XII INTACT. SOMEWHAT UNSTEADY FINGER NOSE.

ADMITTING DIAGNOSIS:

- ACUTE PSYCHOSIS, RULE OUT STEROID-INDUCED. RULE OUT EXACERBATION OF UNDERLYING CEREBRITIS.
- STATUS POST FLU SHOT CEREBRITIS.
- HISTORY OF RECENT DEEP VENOUS THROMBOSIS OF THE LEGS.

STEPHEN C. BREWER, MD

JLB

D: 12/26/98 T: 12/28/98

END OF REPORT

W Document 30-2 IC FOUNDATION

ONE CLINIC CENTER 9500 EUCLID AVENUE CLEVELAND, OHIO 44195 (216) 444-2200 • 1-800-CCF-CARE

DISCHARGE ORDER

ADMISSION DATE DISCHARGE DATE

led 09/24/2004	Page 21 of 40 H5208

2 764 871 4 001

12,30,98 1,5	199	A. MAYS	
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NAME(S) AND PHONE NO.	<u></u>		18 1946
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OTHER PHYSICIAN:			\circ
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PRINCIPAL DIAGNOSIS (REASON AFTER STU	IDV FOR CA	HIGHE ADMISSION!	
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1	<u> </u>	CEPANDOM/EG TI	
OTHER DIAGNOSIS (ALL OTHER CONDITION:	S, INFECTIO	ONS, COMPLICATIONS AFFECTIN	NG TREATMENT OR STAY)
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0. 00101 100 C	SETES	7	
4. <u>PSYCHOSIS - Organ</u>	<u> </u>	8	
5. Manu myclion		9	
OPERATIONS D	DATE	INVASIVE PROCEDURES	DATE
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3.		3.	
4,		4.	
PENDING LAB/XRAY RESULTS:			
DISCHARGE INSTRUCTIONS See attach	and for addit	ional instructions Tentative retur	n to work date
DIET No Restrictions ADA 1 t			
ACTIVITY No Restrictions OR Specify (included)			1).
MEDICATIONS NAME / DOSE / ROUTE / FREQUEN	•		
1. Coumadin 5 mg 90		- 6	·
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3 Remendona Imaba	y po	8	Hen stor
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FOLLOW-UP PHYSICIAN/OTHER	LOCATION	DATE/TIME TO BE SCI	HEDULED PHONE NO.
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PLANNED READMISSION			DATE.
TO:DATE:		DEDURE:	DATE:
I have received a copy of the above instructions and understand	nd them. I have	received my personal balong has and or	valuables slip.
Patient/Significant Other		Registered	Nurse
DISCHARGE SUMMARY DICTATED: TYES	□ NO	1113.11	INA ONTO
DISCHARGE PHYSICIAN: SIGNATURE	* 0 1)	2 N/ CAINT NAME	BEEPER NUMBER

LUANN PARKER,

Case No. C-1-00-766

Plaintiff.

JUDGE Susan J. Dlott

V.

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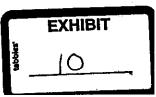
: Affidavit of David A. Griesemer, M.D.

AVENTIS PASTEUR INC.,

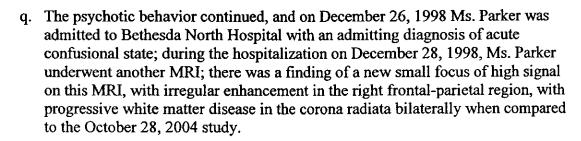
Defendant.

David A. Griesemer, M.D., being first duly cautioned and sworn, deposes and states upon personal knowledge as follows:

- 1. My name is David A. Griesemer.
- 2. I am a physician licensed to practice medicine in the states of Arizona and South Carolina.
- 3. I am board certified in Neurology with Special Competence in Child Neurology and in Clinical Neurophysiology.
- 4. I have attached, as part of this affidavit, my Curriculum Vitae.
- 5. I have reviewed the medical, hospital, and other records of Ms. Luann Parker.
- 6. In my review of Ms. Parker's records I found the following:
 - a. Ms. Parker was free of neurological impairment prior to October 10, 1998.
 - b. Ms. Parker was administered an intermuscular injection of Influenza virus vaccine known as Fluzone® on October 10, 1998.
 - c. On October 12, 1998, following this flu vaccine injection, she developed a severe headache, ataxia, vertigo and tingling in her hands.
 - d. On October 12, 1998, Ms. Parker awoke with pain in her neck and occiput and with dizziness.
 - e. On October 13, 1998, with complaints of numbness in her hands, some difficulty thinking and with more severe headaches, Ms. Parker was taken by ambulance to the emergency room of Bethesda North Hospital.



- f. On October 14, 1998, Dr. Brewer, her primary care physician, referred Ms. Parker to Marvin Rorick, M.D., a neurologist.
- g. On October 15, 1998, she underwent an MRI examination; the finding of the MRI showed a bilateral posterior parietal enhancement, primarily meningeal in location, with additional, multiple small nodular areas in the deep white matter, which were not enhancing.
- h. Dr. Rorick noted in a letter to Dr. Brewer: "This appears to be a mild disequilibrium syndrome which may represent a postvaccination effect."
- i. Ms. Parker was re-admitted to Bethesda North Hospital on October 21, 1998, with a diagnosis of "acute cerebritis" and a secondary diagnosis of "post influenza vaccine reaction."
- j. On October 21, 1998, Dr. Rorick wrote a neurology note that states in part: "Patient is 52 Year old lady in good health until the week of 10/12/1998, within 48 hours of receiving a flu shot at Thriftway in Blue Ash on 10/10. Initial symptoms unsteady gait, numbness in both hands, headache mainly [r] side."
- k. On October 25, 1998, Ms. Parker was discharged from Bethesda North Hospital to home, with a principle diagnosis of "encephalitis following immunization procedures."
- 1. Ms. Parker was again admitted to Bethesda North Hospital on October 27,1998 for increasing ataxia with titubation and an uninhibited voiding problem; the meningeal enhancement on the MRI during this admission was decreasing. The principle diagnosis explaining her admission was "Post Flu shot Cerebritis."
- m. Silvania Ng, M.D., a neurologist, saw Ms. Parker as a consultant on October 29, 1998; Dr. Ng reported in her assessment: "Plan: severe ataxia, Status post flu shot. I did contact the CDC and have talked to Dr. Carolyn Bridges, one of the doctors responsible for the bunch of flu vaccine, and she states that this whole picture could be secondary to the flu shot although is very rare such report . . ."
- n. Ms. Parker was discharged from the hospital on November 9, 1998, two weeks later.
- o. Ms. Parker was again admitted on November 14, 1998 as an inpatient to Bethesda North Hospital with a primary admitting diagnosis of "probable deep vein thrombosis of LT (sic) leg." Ms. Parker was discharged from the hospital on November 17, 1998.
- p. On December 25, 1998, Ms. Parker was taken to the Emergency Room of Bethesda North Hospital with a chief complaint of hearing voices.



- r. On December 29, 1998 Ms. Parker was transferred to the Cleveland Clinic Foundation Hospital, under Dr. M. May's care; during this hospitalization, there was a thorough attempt to rule out other problems causing her neurological symptoms.
- s. Ms. Parker was discharged to her home from the Cleveland Clinic on January 5, 1999 with the principle diagnosis of ADEM.
- 7. On September 16, 2002 I signed an affidavit in this case stating that: based upon my review of Luann Parker's records, I state, within a reasonable degree of medical and scientific certainty, that her symptoms associated with ADEM (acute disseminated encephalomyelitis) were caused by her vaccination received in October of 1998. Furthermore, additional symptoms associated with steroid treatment of ADEM represent secondary effects following the vaccination.
- 8. Since then I have reviewed the neuroimaging studies of Ms. Parker, the Summary of Independent Medical Examination and Expert Report of Dr. Geoffrey Eubank, and the Defendant's Motion for Summary Judgment with the attachment.
- 9. I have also researched and am familiar with the relevant literature concerning the link between vaccinations and ADEM.
- 10. It is still my opinion, based on a reasonable degree of medical and scientific certainty, that Ms. Parker suffered from ADEM resulting from her influenza vaccination. That opinion is based on the medical record and the review of the scientific literature, the diagnosis by several physicians who were treating Ms. Parker, who ruled out other possible causes before concluding that she suffered from ADEM caused by the influenza vaccination.
- 11. The association between influenza vaccine and ADEM is widely accepted and is noted in standard neurology textbooks. Examples of textbooks commonly used in medical schools include:
 - a. Rowland LP, Merritt's Neurology, 10th edition. Philadelphia: Lippincott Williams & Wilkins, 2000, pp. 151-153, which states, "Acute disseminated encephalomyelitis (ADE) may occur in the course of various infections, particularly the acute exanthematous diseases of childhood, and following

- vaccinations." It is associated with "vaccination against measles, mumps, rubella, influenza, and rabies." (emphasis added)
- b. Rust R, and Menkes JH. "Autoimmune and postinfectios diseases." In Menkes, JH, Sarnat HB, eds. Child Neurology, 6th edition. Philadelphia: Lippincott Williams & Wilkins, 2000, pp. 641-645, which states, "ADEM can develop after vaccination with a wide variety of killed or attenuated organisms. These include rabies vaccine, Japanese encephalitis, and influenza vaccines." (emphasis added)
- c. Rust and Menkes also concluded that with ADEM "[m]eningeal inflammation also may be found. Severe cases may show disseminated hemorrhages, a syndrome that has been designated acute hemorrhagic encephalopathy." These are the findings in the case of Ms. Parker.
- d. Osborne AG. Diagnostic Neuroradiology. St. Louis: Mosby Year Book, 1994, p.704, which says, "Acute disseminated encephalomyelitis (ADEM) is an immune-mediated response to a preceding viral infection or vaccination. ADEM occurs in several settings as follows:
 - 1. Shortly after a specific viral illness, particularly exanthematous childhood diseases such as measles or chicken pox
 - 2. Following a non-specific, presumably viral, upper respiratory infection
 - 3. Following vaccination against rabies, diptheria, smallpox, tetanus, typhoid, or influenza
 - 4. Spontaneously" (emphasis added)
- 12. Bale JF. Neurologic complications of immunization. J Child Neurol 2004; 19:405-412, a current review of vaccination effects, indicates that ADEM is a possible effect of the influenza vaccine.
- 13. General principles of clinical epidemiology guide us in defining studies likely to provide a valid answer to whether or not an influenza vaccine can cause ADEM. Ideally, there would be a randomized, placebo-controlled clinical trial, comparing outcomes for patients exposed and patients not exposed to influenza vaccine. The number of patients required to detect important but rare adverse effects, however, would be prohibitive. It is for this reason that no such "epidemiologic evidence" exists. The next best way to answer the question is to conduct a cohort study, comparing a group that received the vaccine with a group that did not. This is a study that follows patients forward in time after receiving a vaccine. Because assignment to the groups is not random, it is impossible to guarantee that both groups are equivalent. Bias in patient grouping is introduced, and problems with infrequent complications requires Herculean effort to detect rare effects. The next most

effective tool is a case-controlled study, in which—after the fact—patients who have the adverse effect are compared to those who do not. The medical literature contains none of these studies. This leaves academic clinicians like myself to depend upon case series or individual case reports in which there is no comparison group. The only thing that can be ascertained from these reports is than an adverse effect can occur (but not necessarily must occur). Therefore, to say that, because no epidemiological studies have been done, no cause and effect relationship exists is not valid.

- 14. In addition, unlike other vaccinations such as MMR and DPT, the influenza vaccination changes from year to year because the strains of influenza change from year to year. Consequently there are a limited number of similar vaccine exposures to accumulate.
- 15. The Defendant's expert's conclusion about the "episode of neurologic dysfunction" is diagnostically inadequate. Without reviewing details of Ms. Parker's medical record or considering contemporaneous impressions of her physicians, he is content to say that she did not have typical ADEM and therefore her illness was not caused by the vaccine. Dr. Eubank fails to offer a plausible alternative diagnosis and he overlooks the temporal relationship between vaccine and illness which must be considered.
- 16. Case studies concerning the association between vaccination and ADEM do appear in medical literature. These include:
 - a. Yahr MD and Lobo-Atunes J. Relapsing encephalomyelitis following the use of influenza vaccine. Arch Neurol 1972; 27:182-183.
 - b. Ehrengut W and Allerdist H. Über neurologische Komplikationen nach der Influenzaschutz-impfung. Münch med Wschr 1977; 119:705.
 - c. Gross WL, Ravens KG, Hansen HW. Meningoencephalitic syndrome following influenza vaccination. J Neurol 1978; 217:219-222.
 - d. Saito H, Endo M, Takase S, Itahara K. Acute disseminated encephalomyelitis after influenza vaccination. Arch Neurol 1980; 37:564-566.
- 17. This medical literature demonstrates that influenza vaccines can cause ADEM.
- 18. Given the temporal relationship between the administration of Defendant's vaccination and the onset of symptoms, it is my opinion that Defendant's vaccine caused Ms. Parker's ADEM.
- 19. In conclusion, I concur with the neurologists at Bethesda North Hospital, the Cleveland Clinic Foundation, and the Centers for Disease Control: Ms. Parker suffered from ADEM caused by the influenza vaccination she received on October 10, 1998.

FURTHER THE AFFIANT SAYETH NAUGHT.

Sand a. Liesena "

David A. Griesemer, M.D.

Sworn to and subscribed before me this 16th day of September, 2004.

Notary public

My Commission Expires March 19, 2013

CURRICULUM VITAE

Name:

David A. Griesemer, M.D.

Birthdate:

January 6, 1951

Home Address:

1207 Southern Oak Way

Phone:

843/849-1474

Mt. Pleasant, SC 29466

Mobile Phone:

843/437-1955

Office Address:

Medical University of SC

Phone:

843/792-3224

Department of Neurology

Fax:

843/792-1763 Email: griesemer@postmaster.co.uk

96 Jonathan Lucas Street Charleston, SC 29425

Citizenship:

USA

Education (beginning with Baccalaureate degree) Institution/Location

Degree/Date

Field of Study

Johns Hopkins University

1969-1972

BA/1972 Cum Laude Human Biology

Baltimore, MD

Johns Hopkins University

1972-1976

MD/1976

Medicine

School of Medicine Baltimore, MD

Internship

Place

Dates

Johns Hopkins Hospital

1976-1977

Baltimore, MD

Residency or Postdoctoral

Place

<u>Dates</u>

Johns Hopkins Hospital

1977-1978

Baltimore, MD

Assistant Resident in Pediatrics

University of Michigan Hospitals

1982-1985

Ann Arbor, MI

Child Neurology Fellow

Specialty/Board Certification

American Board of Psychiatry and Neurology Neurology with Special Competence in Child Neurology 1992 (Certificate 821)

American Board of Psychiatry and Neurology Clinical Neurophysiology 1997 (Certificate 828)

Filed 09/24/2004

David A. Griesemer, M.D. Page 2

Licensure

Maryland (D19541), 1976-1993 Michigan (44935), 1982-1985 Arizona (15236), 1985-present South Carolina (16681), 1993-present

Military Service

Active Duty US Public Health Service Keams Canyon, AZ 1978-1982

Active Reserves US Air Force Reserve Wurtsmith Air Force Base (SAC) Luke Air Force Base (TAC 1982-1989

Years	s (begin with Initial ap <u>Rank</u>	ppointment) Institution	<u>Department</u>
1990-1993	Assistant Professor	University of Arizona College of Medicine Tucson, AZ	Pediatrics; Neurology
1993-1997	Assistant Professor	Medical University of South Carolina Charleston, SC	Neurology; Pediatrics
1997-2002	Associate Professor	Medical University of South Carolina Charleston, SC	Neurology; Pediatrics
2002-present	Tenure	Medical University of South Carolina Charleston, SC	Neurology; Pediatrics
2002-present	Professor	Medical University of South Carolina Charleston, SC	Neurology; Pediatrics

David A. Griesemer, M.D. Page 3

Administrative Appointments

<u>Years</u>	<u>Position</u>	Institution	Department
1980-1982	Director, Keams Canyon Indian Hospital	US Public Health Service Phoenix Area Indian Health Service Keams Canyon, AZ	N/A
1990-1993	Director, Pediatric Epilepsy Unit	Arizona Health Sciences Center Tucson, AZ	N/A
1990-1993	Medical Director	Fan Kane Research Fund For Brain-Injured Children Tucson, AZ	N/A
1992-1993	Medical Director Pediatric Rehab Program	Rehab Institute of Tucson Tucson, AZ	N/A
1993-2000	Director, Pediatric Epilepsy Program	Children's Hospital Medical University of SC Charleston, SC	N/A
1994-2000 2004-present	Director, Clinical Neurophysiology Services	MUSC Hospital Charleston, SC	N/A
2000-present	Chairman, Department of Neurology	Medical University of SC Charleston, SC	Neurology

Hospital Appointments/Privileges Active/Inactive Institution

/ TOUTE / MIGGING	<u>msutation</u>
Inactive	Public Health Service Indian Hospital, Keams Canyon, AZ
Inactive	Yavapai Regional Medical Center, Prescott, AZ
Inactive	Tucson Medical Center, Tucson, AZ
Inactive	University Medical Center, Tucson, AZ
Inactive	Rehab Institute of Tucson, Tucson, AZ
Active	Medical University of South Carolina, Charleston, SC
Inactive	Roper Hospital, Charleston, SC
Inactive	Thad E. Saleeby Development Center, Hartsville, SC
Active	East Cooper Regional Medical Center, Mt. Pleasant, SC

Filed 09/24

2004

Membership in Professional/Scientific Societies (including offices held)

Charleston County Medical Society

National

American Academy of Neurology American Academy of Pediatrics (Fellow), elected member American Epilepsy Society Child Neurology Society Society for Neuroscience, elected member American Academy of Sleep Medicine

Editorial Positions

Johns Hopkins Medical Journal Assistant Editor, 1974-1976

MedLink Neurology (Multimedia Internet and CD-ROM reference for Neurology Associate Editor for Child Neurology, 1997-present

Emedicine: Neurology (Internet reference for neurology and pediatrics) Associate Editor for Child Neurology, 1999-present

Extramural Grants/Award Amounts (current and past)

As Principal Investigator

1994-1996 Gabapentin pediatric monotherapy trial: a multicenter, double-blind, placebocontrolled, parallel group study in pediatric patients with benign childhood epilepsy

with centrotemporal spikes.

Parke-Davis Research Foundation

1995-1998 An extended open-label gabapentin pediatric monotherapy trial following a double-

blind study in pediatric patients with benign childhood epilepsy with centrotemporal

spikes.

Parke-Davis Research Foundation

1995-1996 A double-blind parallel group comparison of gabapentin versus placebo as add-on

therapy for epilepsy in children.

Parke-Davis Research Foundation

1995-1996 An open-label extension study of gabapentin in children with epilepsy who have

participated in the double-blind study 945-186.

Parke-Davis Research Foundation

1995-1997 Efficacy and safety of oral adjunctive vigabatrin therapy compared to placebo in

children with uncontrolled complex partial seizures: A parallel group study.

Hoescht Marion Roussel

David A. Griesemer, M.D. Page 5

Extramural Grants (Continued)

1996-1998 An open-label, follow-up, long-term maintenance study of vigabatrin as adjunctive

therapy in children with uncontrolled complex partial seizures.

Hoescht Marion Roussel

1995-1996 Lamotrigine as add-on therapy in patients with a clinical diagnosis of Lennox-Gastaut

syndrome (severe generalized epilepsy of childhood onset): a multicenter, double-

Filed 09/24/2004

blind, placebo controlled, parallel study. Glaxo Wellcome Research & Development

1995-1996 An open-label study of Lamictal in patients who previously participated in a Lamictal

pediatric trial.

Glaxo Wellcome Research & Development

1999-2000 Gabapentin pediatric add-on trial: A randomized, double-blind, placebo-controlled,

parallel-group, multicenter study in patients with partial seizures.

Parke-Davis Pharmaceutical Research

1999-2000 Open-label, safety study of gabapentin as adjunct therapy in children aged 1 month

through 4 years with seizures uncontrolled by current anticonvulsant drugs.

Parke-Davis Pharmaceutical Research

A 19-week, randomized, double-blind, multicenter, placebo-controlled safety study to evaluate the cognitive and neuropsychological effects of levetiracetam as adjunctive

treatment in children with refractory partial onset seizures.

UCB Pharma

A multicenter, open-label, long-term follow-up study of the safety and efficacy of

levetiracetam in children with partial onset seizures.

UCB Pharma

Intramural Grants/Award Amounts

As Principal Investigator

1992-1993 Language impairment in children with focal epileptic discharges

Biomedical Sciences Research Grant University of Arizona College of Medicine

1994-1997 Electroconvulsive therapy for intractable seizures in children (HR#6244)

Medical University of South Carolina

1995-1996 Neurologic morbidity and development following elective circulatory arrest in

infants (HR#6379)

Medical University of South Carolina

1996 - 1998 Determination of multi-modality evoked potentials at MUSC (HR#6641)

Medical University of South Carolina

1997-1999 Sleep disorders in children with epilepsy (HR#7215)

Medical University of South Carolina

David A. Griesemer, M.D.

Page 6

As Co-Investigator

1997-2000

Lovastatin therapy for X-linked adrenoloeukodystrophy (HR#7210)

G. Shashidhar Pai, MD, PI

Medical University of South Carolina

As Consultant

2000-2001

Learning impairments among survivors of childhood cancer (HR#8351)

R. Brown, PhD, Pi

Medical University of South Carolina

2003-

Pediatric hydroxyurea Phase III clinical trial (BABY HUG) Julio Barredo, MD, PI (Medical University of South Carolina)

National Heart, Lung and Blood Institute

South Carolina epidemiological studies of epilepsy and seizure disorders

Anbesaw Selassie, PhD, Pl (Medical University of South Carolina)

CDC / National Center for Injury Prevention and Control

Awards/Honors/Membership in Honorary Societies

1980

Isolated Hardship Award US Public Health Service Keams Canyon, AZ

1987

Achievement Medal for Meritorious Service

US Air Force Washington, DC

1992

Dean's Teaching Scholar

University of Arizona College of Medicine

Tucson, AZ

1993

Virginia Furrow Grant for Innovation in Medical Education

University of Arizona College of Medicine

Tucson, AZ

1993

Neurology Teaching Award Department of Neurology

University of Arizona College of Medicine

Tucson, AZ.

2000

Award of Tenure, College of Medicine Medical University of South Carolina

Charleston, SC

2001-2004

Jeffrey E. Gilliam Chair in Child Development

Medical University of South Carolina

Charleston, SC

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Extramural Professional Activities

American Academy of Neurology Residency Inservice Examination Subcommittee 1998-2001

Child Neurology Society **Practice Committee** 1999-present

Publications

Peer Reviewed Journal Articles

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- 3. Griesemer DA, Talwar D, Hadden RO, Johnson MI, Baldwin MA. Reflex apnea with autonomic dysynergy (RAAD). *Epilepsia* 1993;34(Supplement 6):43.
- 4. Talwar D, Baldwin MA, Griesemer DA. Epileptic spasms in older children: Persistence beyond infancy. *Epilepsia* 1993; 34(Supplement 6):37.
- 5. Griesemer DA, Baldwin MA. Munchausen-by-proxy epilepsy in foster families. *Epilepsia* 1994; 35(Supplement 8):56.
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- 7. Talwar D, Weinand ME, Baldwin MA, Labiner DM, Griesemer DA, Oomen KJ. Surgical treatment of intractable symptomatic occipital epilepsy. *Epilepsia* 1994;35(S8):69.
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- Griesemer DA. Muscular dystrophy. In: Griffith's 5 Minute Clinical Consult, (Dambro MR, Griffith J. eds), Williams-Wilkins/Philadelphia PA, 1995:690-691; 1996:690-691; 1997:698-699; 1998:700-701.
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- 1. Griesemer DA. Focal cortical dysplasia. In: Neurobase (Gilman S, Goldstein G, Waxman S, eds), Arbor Publishing Corp/La Jolla, CA, 1995.
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- 18. Griesemer DA, Sobczak JM. Craniosynostosis. In: *MedLink Neurology*, (Gilman S, ed), MedLink Corp/San Diego CA, 2001.
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Other

- 1. Griesemer DA. A Textbook of Epilepsy, by Laidlaw and Richens [book review]. Johns Hopkins Med J 1977; 141:301
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Re: Luann Parker June 10, 2004 Page Two

status appeared normal. We did a Folstein Mini-Mental Status Examination, which was normal, with the exception that she was not aware of the county (she is not from this county, however). Her clock drawing was normal. She was able to generate a word list of 27 animals in 1 minutes (above normal). She was able to describe proverbs and similarities without difficulty. There are no signs of apraxia.

Review of her testing revealed that her original MRI scan, in October of 1998, had scattered fool of abnormal signal in the periventricular white matter and also in the high parietal region. There was some enhancement in these lesions. These are more pronounced on the December scan (1998). There is also left meningeal thickening and enhancement in the parietal regions and there are even some areas of possible hemorrhage. He repeated her MRI scan on February 26, 1999, which showed a new area of signal abnormality, that was felt to be likely petechial hemorrhage change with some new enhancement in the left thatamus.

It should be noted that she had some mild atrophy noted, even on her original MRI.

Multiple tumbar punctures were done and did not show any significant abnormalities. Specifically, she had fewer white cells, normal protein, normal IgG synthesis rate and negative cultures. She had a number of other tests, the relevant abnormalities being, at one time, she had an elevated sedimentation rate and C-reactive protein. She also was found to have antiplatelet antibodies, suggestive of idiopathic thrombocytopenic purpura (ITP). She was also diagnosed with a DVT and was noted to have a factor V leiden.

She had a cerebral angiogram that did not show any significant abnormalities,

In summary. Luann Parker had an episode of neurologic dysfunction, manifest by headache, whole body numbness and apparent seizure and some mental status changes. She was treated with steroids along the way. It was unclear, from the various examining physicians, exactly what she had. The possibility of acute demyelinating encephalomyelitis was posed as a possible explanation, although I think that it not a tenable diagnosis here. She had a neurologic syndrome that showed evidence for active changes five months into the illness, which is not at all typical (in fact not characteristic) of acute demyelinating encephalomyelitis (ADEM). This is a monophasic illness, rather than a prolonged illness, such as this, Symptoms, going on for a few weeks at most, are typical and not several months. That is not to say that the clinical symptoms cannot be residual but, certainly, progressive problems and, more importantly, progressive MRI abnormalities would not fit with the diagnosis. I don't think a formal diagnosis was made and that was evident by the various neurologists, who saw her, and their uncertainty

In summary, I don't believe that Luann Parker had ADEM, for the reasons described. I am not aware of any studies suggesting that the flu vaccine is causative of ADEM and, in this case, given the absence of a diagnosis of ADEM, I think it is a moot point, anyway.

Warmest regards,

Scoffrey A. Eubahk, M.D.

GAE:jim

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Main Office; Chatham Village Professional Buliding

931 Chatham Lana Colombus, OH 43221 (614) 457-4880 Fax (614) 457-4890

(800) 527-9022

MMM.neuroazzociałez.com

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Edanird J. Konrik.
M.D., F.A.C.S., F.A.A.P.
Michael J. Meaglier, M.D.
Janei W. Bay, M.D.
Sigurdur A. Stephensen,
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Scott W. Elton, M.D.
Mark A. Hnillen, M.D.
Ward P. Buster, D.O.
Rebecca F. Brightman,
M.D., F.A.C.S.

Pediatric Neurosurgery

Edward J. Kosnik, M.D., F.A.C.S., F.A.A.P. Scutt W. Biton, M.D.

Adult Neurology

Robert FL. Wwitt, M.D., A.D.P.N. Albert L. Bernrducel, Jr., M.D., A.B.P.N. Geiffrey A. Eubank M.D., A.B.P.N.

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Janua P. Fulay,

M.D., A.B.P.N., A.B.S.M.

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Spine Physiatrial and Pain Consultant Youward P. Reddy, M.D.

Parinets Emerilus

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SUMMARY OF INDEPENDENT MEDICAL EXAMINATION AND EXPERT REPORT

DATE: September 2, 2004

PATIENT: Luann Parker

HISTORY: Luann Parker is a 58-year-old right-handed woman who was here on June 10, 2004 for an independent medical examination. She states that on October 10, 1998, she had a flu shot at a grocery store. She had multiple flu shots prior to this and never had any difficulty. She states that, within a few days of that injection, she had some confusion. She was driving and was unsure where to turn. She also felt that there was a sense of internal numbness throughout her body. She was able to move with this. She ended up calling 911 and went to the hospital. She told them she felt detached from her limbs. She is unsure of the diagnosis from the emergency room, but thinks they inferred that she had some sort of emotional breakdown and was sent home. Over the next few months, she had progressive difficulties. On one occasion, she was admitted to the hospital and was witnessed to have some sort of seizure, although she is not exactly what type. She also was having some gait difficulty of an unspecified type. She felt that her memory was not good. She entered the hospital several times and these symptoms kept worsening. She even was having difficulty sitting. She even had difficulty putting the covers over her and being able to tell time. At times, she would do some behaviors, such as rocking behavior. Her mother had died around this same time. Shortly after that, she became "psychotic", according to her sister. She stated that, on Christmas, she saw her "then-dead" mother coming in on a sunbeam. At that time, she was rocking very quickly. It was at that time, that the family requested her to be transferred and she was sent up to the Cleveland Clinic.

While at the Cleveland Clinic, she continued to have mental status changes and they were told that she had some sort of psychosis. She continued to have decreased memory. Things ended up stabilizing while she was up there and she gradually improved, to the point where she is now, two years later. Even a year afterward, she was still having difficulty coping and difficulty driving, because she couldn't process "too much information". She was unable to multitask. Today, she is fully independent and is back working. She still has some subtle residual difficulty, such as choking on her food, on occasion. She also feels that her left side is slightly weak or clumsy. She has a headache most mornings, but that does not pensist. She feels that her recall is a little slow. She also feels a general sense of imbalance. She denies fevers, chills, weight loss, ongoing visual difficulty, hearing difficulty, chest pain, palpitations, bowel/bladder change, tremor, ongoing selzures, numbness, loss of consciousness or depression.

She has history of hypertension, high cholesterol, diabetes, migraines and blood clots. The latter is due to a factor V mutation. She takes Lipitor and Cournadin. Codeine makes her vomit.

She does not smoke or drink. She notes no neurologic problems in the family, with the exception of migraine,

EXAMINATION: 8P 140/90, P-80, R-16. She is well nourished and in no acute distress. Funduscopic exam was benign. Her heart was regular without murmurs. There were no cranicervical bruits. Cranial nerves were intact. Her motor examination showed no true neurologic weakness. There was some slight giveaway weakness in her left arm, but normal power was able to be demonstrated. Finger-to-nose and heel-to-shin testing and rapid alternating movements were all normal. Galt was normal. A Romberg was negative. Sensation to pinprick, light touch, temperature and vibratory were all normal. Her reflexes were 2+ and symmetric throughout. Toes were downgoing. Her mental

EXHIBIT